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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,123

12/30/2003

David M. Gravett

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

04/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/749,123

Applicant(s)

GRAVETT ET AL.

Examiner

Jagadishwar R. Samala

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-240 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-240 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-153 are, drawn to a composition comprising a synthetic polymer and a drug, the polymer comprising multiple activated groups, classified in class 424, subclass 486, 488.
  - II. Claims 154-172 are, drawn to a method of affecting biological processes in vivo, classified in class 424, subclass 486, 488.
  - III. Claims 173-184 are, drawn to a method comprising contacting tissue in vivo with a synthetic polymer comprising multiple activated groups, where the activated groups are tissue-reactive and synthetic polymer is covalently adhere to the tissue, classified in class 424, subclass 486,488.
  - IV. Claims 185-196 are, drawn to a method comprising: contacting a non-living surface with a synthetic polymer comprising multiple activated groups, where the activated groups are tissue-reactive and synthetic polymer is covalently adhere to the surface, classified in class 424, subclass 486,488.
  - V. Claims 197-203 are, drawn to a method for preparing a reactive composition, providing a synthetic polymer comprising multiple activated groups, combining with buffer to raise the pH and to form a homogeneous solution, classified in class 424, subclass 486,488.

- VI. Claims 204-212 are, drawn to a method of adhering a synthetic polymer to in vivo tissue, the method comprising various steps, classified in class 424, subclass 486,488.
- VII. Claims 213-224 are, drawn to a composition comprising: a synthetic polymer comprising multiple activated groups; and an aqueous buffer; wherein the composition is a homogeneous solution having a pH of less than 6, classified in class 424, subclass 486,488.
- VIII. Claims 225-232 are, drawn to a method of coating a device comprising: applying a multifunctional hydroxysuccinimidyl PEG derivative to the surface of the device and allowing the derivative to react with functional groups on the device surface, classified in class 424, subclass 486,488.
- IX. Claims 233-240 are, drawn to a method of reducing surgical adhesions comprising applying a multifunctional hydroxysuccinimidyl PEG derivative to a tissue surface, classified in class 424, subclass 486,488.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I (& VII) and II (or III-VI & VIII-IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case group I and VIII are drawn to a composition comprising a synthetic polymer

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containing multiple activated groups and a drug and group II (or III-VI & VIII-IX) are drawn to method of using the product, yet group II or (III-IX) can be practiced with materially different product.

3. Inventions III-VI & VIII-IX are directed to patentably distinct products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design, mode of operation, function, or effect.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The instant invention comprises five distinct components. Each component is listed as follows. Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species from each component** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The species are patentably distinct because each component has chemically different core structure, which may not be related or may not share same structure core.

- (1) A synthetic polymer chosen from the following:
  - (a) Cyclic core as recited in claim 2-6.
  - (b) Branched chain core as recited in claim 7-14.
  - (c) Activated groups as recited in claim 26.
- (2). A activated groups chosen from the following:
  - (a) Protein-reactive
  - (b) Hydroxyl group
  - (c) Thiol group
  - (d) Amino group
  - (e) Electrophilic site
  - (f) Carbonyl group
  - (g) Leaving group
- (3) A formula (polymer backbone)-(Q-Y), wherein Q is a linking group consisting of  $-G-(CH_2)_n$  and G is chosen from following :
  - (a) Oxygen
  - (b) Sulphur
  - (c) -NH group
  - (d) -O-CO- and O-CO-NH-(CH<sub>2</sub>)<sub>n</sub>
  - (e) -O<sub>2</sub>C-CR<sup>1</sup>-H
  - (f) -O-R<sup>2</sup>-CO-NH

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(4) A formula (polymer backbone)-(D-Q-Y), wherein D is a biodegradable group chosen from following

- (a) Lactide
- (b) Glycolide
- (c) Epsilon-caprolactone
- (d) Poly (alpha-hydroxy acid)
- (e) Poly (amino acid)
- (f) Poly (anhydride)
- (g) Poly (orthoester).

(5) A composition comprising drug, wherein drug is chosen from following:

Composition comprising drug, wherein drug is an angiogenesis inhibitor, Lipoxygenase inhibitor or antagonist, chemokine receptor, cell cycle inhibitor, cyclin dependent protein kinase inhibitor, EGF kinase inhibitor, elastase inhibitor, factor Xa inhibitor, farnesyltransferase inhibitor, fibrinogen antagonist, guanylate cyclase stimulant heat shock protein 90 antagonist HMGCoA reductase inhibitor, hydroorotate dehydrogenase inhibitor, IKK2 inhibitor, IL-1, ICE, or IRAK antagonist, IL-4 agonist, immunomodulatory agent, inosine monophosphate dehydrogenase inhibitor, leukotrene inhibitor, MCP-1 antagonist, MMP inhibitor, NF-kappa B inhibitor, NO antagonist, P38 MAP kinase inhibitor, phosphodiesterase inhibitor, TGF beta inhibitor, and like as recited in claims 75-137.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Due to complexity of the restriction requirement, telephone call was not made to applicants.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of



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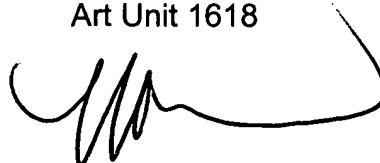
record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagdishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VICKIE KIM  
PRIMARY EXAMINER  
Jagdishwar R Samala  
Examiner  
Art Unit 1618



sjr